

# The Role of the HHS Office of Inspector General

Summit on Disclosure, Transparency,  
and Aggregate Spend  
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# Office of Inspector General (OIG)

- Separate Agency within HHS
- Inspector General Act of 1978
- Mission:
  - ◆ Promote economy, efficiency in HHS programs
  - ◆ Prevent, detect fraud and abuse in HHS programs

# HHS-OIG: The Basics

- Over 1500 employees
- Washington, DC headquarters
- Components of particular interest:
  - ◆ Office of Evaluations and Inspections (OEI)
  - ◆ Office of Audit Services (OAS)
  - ◆ Office of Investigations
  - ◆ Office of Counsel

# Relevant OIG Work

- Reports by OEI, OAS
- Hearing Testimony
- OIG Work Plan
- Fraud and Abuse Work

OIG website: [www.oig.hhs.gov](http://www.oig.hhs.gov)

# OIG Role in False Claims Act Cases

- Increasing numbers of False Claims Act (FCA) cases against drug and device manufacturers
- Work with Department of Justice (DOJ)
  - ◆ Represent HHS interests
  - ◆ Intervention/declination recommendations
  - ◆ Coordination within HHS

# OIG Role in Settlement of False Claims Act Cases

- Signatory on behalf of HHS
- Resolution of Exclusion Issues
- Negotiation of Corporate Integrity Agreements (CIAs)

# Authority for Exclusions

- Section 1128 of the Social Security Act (42 U.S.C. § 1320a-7)
- 42 C.F.R. Part 1001
- Other authorities, *e.g.*, CMPs
- Independent of DOJ

# Exclusions: Mandatory and Permissive

- Mandatory- 42 U.S.C. § 1320a-7(a)
- Permissive- 42 U.S.C. § 1320a-7(b)
- Applies to Indirect Providers (including Drug and Device Manufacturers)



# Corporate Integrity Agreements

- Generally required if exclusion waived
- Our Principle: continued participation in HHS programs with appropriate controls
- Considerations:
  - ◆ Nature of underlying conduct
  - ◆ Potential for future risk
  - ◆ Effectiveness of compliance program

# Corporate Integrity Agreements

- Typically, a 5-year term
- Requires several measures, including:
  - ◆ Compliance Officer/Committee
  - ◆ Code of Conduct/Written Policies
  - ◆ Training
  - ◆ Audits
  - ◆ Reports to OIG

# “Enhanced” CIA Provisions

- Requirements Designed to Increase Transparency
  - ◆ Notification of HCPs about settlement
  - ◆ Posting of Payment Information on Manufacturer’s website
    - ◆ Broad Definition of “Payments”
    - ◆ Interplay with Federal Legislation

# “Enhanced” CIA Provisions

- Requirements Designed to Increase Accountability
  - ◆ Annual Board Resolutions
  - ◆ Certifications from Management Team

# Recommendations

- Support/Embrace Transparency
  - ◆ Comprehensive Commitment to Transparency
    - ◆ About detailing relationships with HCPs
    - ◆ About consulting/contractual arrangements
    - ◆ About research activities
    - ◆ About educational activities
    - ◆ About publication activities

# Recommendations

- Support/Embrace Transparency
  - ◆ Establish systems and processes to collect and aggregate payment information
  - ◆ Make payment information publicly available
  - ◆ Post research results
  - ◆ Post grants information

# Potential Outcomes?

- Better compliance with law
- Enhanced public trust
- Improved public health
- Business benefits

